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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,116	11/20/2001	John H. Healey	9958-004-999	6037

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EXAMINER

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/890,116

Applicant(s)

HEALEY ET AL.

Examiner

Donna A. Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,8.                      6) ☐ Other:

**DETAILED ACTION**

***Claims 1-37 are presented for examination.***

***Information Disclosure Statement***

The information disclosure statement filed on 20 November 2001 in paper number 4 has been reviewed and considered. See enclosed copy of PTO FORM 1449.

The information disclosure statement filed on 11 March 2002 in paper number 5 has been reviewed and considered. See enclosed copy of PTO FORM 1449.

The information disclosure statement filed on 23 October 2002 in paper number 8 has been reviewed and considered. See enclosed copy of PTO FORM 1449.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 6-12, 23-24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Keefe et al. U.S. 6,010,711 (AR).

The claims are drawn to a composition and method of making such composition comprising an inorganic bone cement dough and an anti-resorptive agent such as a bisphosphonate or a proteinaceous agent such as a cytokine and wherein the anti-resorptive agent is coats the bone-cement dough or is impregnated in the bone cement dough.

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O'Keefe et al. teach compositions which inhibit bone resorption comprising active agents such as cytokine-suppressing active agents and bisphosphonates in bone cements that are either coated with the agents or admixed directly into the cement. The bone cement recited is methylmethacrylate bone cement (column 2, line 57 to column 4, line 3).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehtinen U.S. Patent No. 5,733,564 A (AL).

The claims are drawn to a bone graft impregnated with an anti-resorptive agent such as a bisphosphonate

Lehtinen teaches bisphosphonate added to solution used for preservation of endo-osteal materials such as artificial joints, hip prostheses, dental and other implants (column 2, lines 25-36). Lehtinen teaches that bisphosphonate's main effect is their ability to inhibit bone resorption (column 3, lines 21-23). Regarding grafts, bisphosphonate treated rabbit tibia was transplanted. Clodronate (a bisphosphonate) treated tibias were more quickly and more extensively vascularized than the control tibias. It does not teach pamidronate, etidronate and alendronate as the bisphosphonate. It would have been obvious to substitute pamidronate, etidronate or alendronate as in the instant application since the clodronate of the reference is a bisphosphonate as well. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezei* 158 USPQ 99; the express suggestion to substitute one equivalent for

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another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532.

Claims 1-16 and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Keefe et al. U.S. 6,010,711 A (AR) in view of Mao et al. U.S. 6,238,687 B1.

The claims are drawn to a moldable composition comprising a bone cement dough, an inorganic bone cement dough and a bisphosphonate or gallium as an anti-resorptive agent.

O'Keefe et al. teach compositions which inhibit bone resorption comprising active agents such as cytokine-suppressing active agents and bisphosphonates in bone cements that are either coated with the agents or admixed directly into the cement. The bone cement recited is methylmethacrylate bone cement (column 2, line 57 to column 4, line 3). O'Keefe et al. does not teach gallium as a further anti-resorptive agent and it does not teach chemotherapeutic and estrogenic agents.

Mao et al. teach polymeric materials that can be used to produce surgical devices such as molded appliances (column 7, lines 4-12). The polymers can be used in a composition containing an active substance and can be used to produce a bone cement for repairing injury to bone (column 21, lines 10-16). The active substance can be antineoplastics such as methotrexate and doxorubicin (column 22, lines 4-40) and hormonal substances (column 22, lines 43-54). Other substances include gallium nitrate (column 23, line 8). The biologically active substance can also include cytokines (column 23, lines 35-38) which can be incorporated in the matrix (impregnated) (column

23, lines 44-67). It would have been obvious to incorporate gallium into bone cement. Motivation comes from the teaching of Mao et al. that recite that gallium is useful in the composition of bone cement as a further active agent. It would have been obvious to incorporate estrogenic and chemotherapeutic agents into the bone cement. Motivation comes from the teaching of Mao et al. that recite that estrogenic agents and chemotherapeutic agents are useful in the composition of bone cement as an active agent.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 8:00 A.M. - 4:30 P.M..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Donna Jagoe  
Examiner  
Art Unit 1614

dj   
March 10, 2003